DEPARTMENT OF HEALTH AND HUMAN SERVICES 94762d Public Health Service

Food and Drug Administration
Florida District
555 Winderley Place
Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
FAX: 407-475-4769

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-04-28

April 13, 2004

Manuel A. Casanova, President
Florida Fisheries Enterprises Inc.
1610 West 31st Place
Hialeah, Florida 33012

Dear Mr. Casanova:

We inspected your firm, at the above address, on January 29, 30 and February 2, 2004, and found that you have serious deviations from the seafood HACCP regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 342(a)(4). Accordingly your fishery products are adulterated, in that the histamine-forming fish and canned pasteurized crabmeat have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You can find the Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviation is as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and you must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a), and (b). However, your firm does not have HACCP plans for canned pasteurized crabmeat to control the food safety hazard of pathogen growth and toxin formation, specifically *Clostridium botulinum*.

In addition, you must have a HACCP plan that, at a minimum, lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for scombroid (histamine-forming) fish lists a monitoring procedure at the Storage critical control point that is not adequate to control the food safety hazard of histamine formation. Your plan states that you will monitor cooler temperatures at least ~~times~~ during the day. The FDA does not consider intermittent temperature checks during storage periods to be an adequate method of assuring that histamine-forming fish are held at safe temperatures

throughout storage. If your products are not stored with ice or cooling media, FDA would expect some method of continuous temperature monitoring such as a time/temperature data logger, recorder thermometer or a high temperature alarm with 24 hour monitoring. This monitoring frequency would be continuous by the instrument itself with a visual check of the instrument at least once per day. If all of your histamine-forming fish products are stored completely surrounded with ice or cooling media, monitoring the adequacy of the ice twice a day is considered the preferable method given those storage conditions. Your current monitoring procedure is also not adequate for storage of canned pasteurized crabmeat where the same concern regarding safe temperatures during storage would apply.

During our inspection, the investigator collected a product list entitled "Item Listing" provided by your Vice President, Iris Casanova. Upon compliance review of this list, it appears that your firm handles additional fishery products that may require additional HACCP plans. For example, the list appears to include refrigerated, ready-to-eat products such as cooked shrimp salad which has a pathogen growth/toxin formation hazard. You should perform a hazard analysis on any and all fish or fishery products handled by your firm, regardless of frequency or quantity received, to determine the food safety hazard(s) and establish a HACCP plan, when necessary.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct these deviations.

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as new or revised HACCP plans or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Shari H. Shambaugh, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Ms. Shambaugh at (407) 475-4730.

Sincerely,

for Emma R. Singleton
Director, Florida District